



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

m4290v

Telephone (973) 526-6008

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

WARNING LETTER

**Certified Mail
Return Receipt Requested**

File # 01-NWJ-01

October 12, 2000

Mr. Mort Waxler
President
Foods Galore, Inc.
9246 Commerce Highway
Pennsauken, NJ 08110

Dear Mr. Waxler:

We inspected your warehouse located at the above address on September 14, 2000 and found serious violations of the Seafood Hazard Analysis and Critical Control Point or HACCP regulations (Title 21, Code of Federal Regulations or CFR, Part 123) and the regulations covering the Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food (21 CFR 110). Those violations described below, cause your products referenced below to be adulterated under the Federal Food, Drug and Cosmetic Act (the Act). The violations were:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for the Don's and Sunnyside brand food products (seafood salad, shrimp salad, tuna salad, tuna pasta salad, chopped herring) you store to control pathogenic food safety hazards. In addition, your firm does not have a HACCP plan for the storage of vacuum packaged smoked nova belly, kippered salmon, plate carp, nova sides, regular sides, and white sable to control the food safety hazard of *Clostridium botulinum* proliferation and toxin formation.
2. You must adequately monitor and document sanitation conditions and practices to comply with 21 CFR 123.11(b) and (c). The sanitation conditions in question are a) the protection of your refrigerated and frozen seafood products from adulteration by chemical, physical and/or microbiological contaminants, b) the exclusion of pests from your facility, and c) the proper labeling, use and storage of toxic compounds. Bird excreta were observed adhering to cases of dried pasta products. Live bird activity was seen within the warehouse.

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3. Once your HACCP plans have been authored, you must monitor and verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). Currently, you are not monitoring refrigeration temperatures where your seafood products are stored. In addition, you are not calibrating temperature devices on your cooler to ensure that temperatures are accurate for subsequent monitoring and recording.
4. You must have an individual (either employed by your firm or as a consultant) trained in the principles and applications of HACCP, to comply with 21 CFR 123.10. That training must be either a result of attending and completing an FDA recognized curriculum or extensive job experience. Currently, you have no HACCP trained individual employed or affiliated with your firm.

In addition, our investigators noted opened single-use food containers and dried pasta products on the floor throughout the warehouse. This serves as an attractant for pests.

The failure to prepare HACCP plans, control food safety hazards, monitor sanitation SOP's, and establish a person or persons trained in HACCP are recurring violations. We previously informed you about those violations in a FDA-483 issued on April 19, 1999 and in a letter from this office, dated August 13, 1999.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP regulations, and the current good manufacturing practice for human food. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

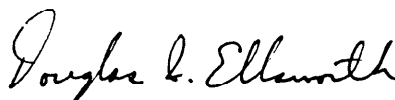
You should take prompt action to correct the violations listed above, as well as any other deviations you have knowledge of. Corrections should include the establishment or refinement of HACCP controls, procedures, monitoring, and training designed to prevent future violations. If you fail to promptly correct these violations, we may take further action to seize your products, enjoin your firm from operating, or criminally prosecute your firm and/or responsible individuals.

We also encourage you to contact Mr. Robert McCullough, Supervisory Investigator, at 856-783-1420, to inquire about HACCP training opportunities.

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Please respond in writing within 15 days from receipt of this letter. Your response should outline the specific steps you are taking to correct the deviations. Please send your reply to the attention of Kirk D. Sooter, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Boulevard, Third Floor, Parsippany, NJ 07054. If you have any questions regarding any issue in the letter, please contact Mr. Sooter at 973-526-6008.

Sincerely yours,



Douglas I. Ellsworth